



Docket No. MCP-281

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : BUNICK, et al.
Serial No. : 09/896,052
Filed : 06/29/2001
Title : BRITTLE COATING, SOFT CORE DOSAGE FORM

Art Unit : 1615
Examiner : Oh, Simon J.

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December 7, 2003

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APPEAL BRIEF

Dear Sir:

In accordance with the provisions of 37 CFR § 41.31, a timely Notice of Appeal was filed in the captioned application on October 20, 2004. Accordingly, this Appeal Brief is timely filed, with an executed Certificate of Mailing on or before December 20, 2004.

Real Party in Interest

The real party in interest in the application in this appeal is Applicants' assignee McNeil-PPC, Inc., a corporation of New Jersey, a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation.

Related Appeals and Interferences

No related appeals or interferences are known to exist.

Status of the Claims

Claims 1-25 are the claims on appeal, a copy of which are attached hereto in the Claims Appendix to this Brief. No claims have been withdrawn. No claims stand allowed in this application.

Status of Amendments

No amendment has been filed subsequent to the final rejection.

Summary of the Claimed Subject Matter

The present invention provides a texture masking oral dosage form comprising (a) a unitary soft core comprising a plurality of active agent (various locations throughout the specification at, for example, p. 3, ln. 28 – p. 7, ln. 13) particles (various locations throughout the specification at, for example, p. 7, ln. 14) having an average size of greater than about 50 μm (various locations throughout the specification at, for example, p. 7, ln. 14-17) and (b) a brittle shell (various locations throughout the specification at, for example, p. 10, ln. 27-p. 12, ln. 5), encasing the soft core (various locations throughout the specification at, for example, p. 8, ln. 1 – p. 10, ln. 26), wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0 in the texture masking oral dosage form (various locations throughout the specification at, for example, p. 7,lns. 27-28 and p. 10, ln. 30-p. 11, ln. 2).

The present invention is also directed to a texture masking oral dosage form comprising (a) a unitary soft core comprising a plurality of acetaminophen (various locations throughout the specification at, for example, p. 4, ln. 28) particles having an average size of greater than about 50 μm and (b) a brittle shell enveloping the soft core, wherein the weight ratio of active agent to shell being from about 1.0:4 to about 1.0:9 in

the texture masking oral dosage form (various locations throughout the specification at, for example, p. 7,lns. 27-28 and p. 10, ln. 30-p. 11, ln. 2).

The present invention is further directed to a texture masking oral dosage form comprising (a) a unitary soft core comprising a plurality of ibuprofen (various locations throughout the specification at, for example, p. 6, ln. 1) particles having an average size of greater than about 50 μm and (b) a brittle shell enveloping the soft core, wherein the weight ratio of particles to shell being from about 1.0:4 to about 1.0:915 in the texture masking oral dosage form. (various locations throughout the specification at, for example, p. 7,lns. 27-28 and p. 10, ln. 30-p. 11, ln. 2).

The present invention is further directed a texture masking oral dosage form comprising (a) a unitary soft core comprising a plurality of active agent particles having an average size of greater than about 50 μm and (b) a brittle shell encasing the soft core, wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0:15 (various locations throughout the specification at, for example, p. 7,lns. 27-28 and p. 10, ln. 30-p. 11, ln. 2) and wherein the soft core has a hardness of about 1 to about 8 kp/cm² in the texture masking oral dosage form (various locations throughout the specification at, for example, p. 9, ln.5-7).

Grounds of Rejection to be Reviewed

Claims 1-25 stand rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. No. 6,060,078 (Lee) in view of U.S. Pat. No. 6,139,865 (Friend).

Argument

Rejection under 35 USC § 103

For the reasons set forth below the rejection, respectfully is traversed.

Lee discloses a chewable tablet a core containing a medicament in a state of jelly or chewable base; and an outer layer of chewable base wrapping the core. (Col. 1, ln. 65 – col. 2, ln. 3.) Lee discloses that a conventional chewable tablet has problems to take because of granular chew and chalky taste in the mouth where the invention “has a good taste and nice chewing property.” (Col. 1, lines 33-35 and 46-52.) The medicament in the core was disclosed as being of bitter taste. (Col. 2, lns. 4-5.) Acetaminophen was disclosed as possibly being contained in the core. (Col. 2, lines 9-18.) According to Lee,

the jelly base of the core, which contains the above medicament in a state of jelly, may be selected from the group consisting of pectin, sorbitol, maltitol, isomalt, liquid glucose, sugar, citric acid and a flavoring agent. (Col. 2, lns 29-32.) According to Lee, the chewable tablet provides taste mask effect to a bitter tasty medicament, which is contained in the medicament, and better chewing property and taste than the conventional tablets by means of an outer tasty chewable base. (Col. 3, lns. 54-57.)

Friend discloses a taste-masked microcapsule composition for administration of a drug. (Abst.) The drug is coated using a coacervation technique in which the drug is coated with relatively high levels of a polymeric material. (Abst.) The technique involves three phases: the core material phase of the drug to be encapsulated, a coating phase of the drug coating substance and a liquid phase in which the core and the coating materials are dispersed or dissolved. (Col. 1, lns. 54-60.) Data are provided that show average and median scores for microencapsulated ranitidine tablets for taste masking, bitterness, aftertaste and overall acceptance. Figs. 3A-3D and 4A-4D. According to Friend, the particle size of the microcapsules can be in the range of a few microns to a thousand microns or more. (Col. 8, lines 31-36.)

In making the rejection, the Examiner asserted that "Lee teaches a chewable pharmaceutical dosage form comprising a core containing an active ingredient and an outer layer." (Paper No. 20031222 at 2.) The Examiner contended that "the dosage form demonstrates improved organoleptic properties when chewed, such as taste. (*Id.*) The Examiner asserted that the "core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin." The Examiner further asserted that gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form. The Examiner stated that the "outer layer may take a variety of forms, including hard candy and that acetaminophen is listed as a possible active ingredient in core. The Examiner concluded that Lee contains and enabling disclosure of a dosage form with a unitary core.

The Examiner contended that Friend "teaches taste-masked microcapsule compositions for the administration of a drug," including acetaminophen and ibuprofen. (Paper No. 20031222 at 3.) The Examiner further contended that Friend discloses that "[t]he compositions may be incorporated into a variety of dosage forms, including

chewable tablets, in amounts ranging from 10% to 95% by weight of the dosage form.” The Examiner further asserted that Friend discloses that “preferred [] microcapsules range in size from approximately 30 microns to 800 microns.”

The Examiner asserted that both Lee and Friend “deal with the administration of drugs in pharmaceutical compositions with improved organoleptic properties.” The Examiner reasoned that “one of ordinary skill would be motivated to incorporate the composition disclosed in Friend into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug.” The Examiner then concluded that “it would have been obvious to one of ordinary skill in the art to combine the teachings of Lee and Friend into the objects of the instant application. (Paper No. 20031222 at 3.)

The Examiner then opined that “[a]s Friend states that the disclosed compositions may be incorporated in chewable tablets, it is the position of the Examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success.”

The Examiner cited *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971) for the proposition that an obviousness analysis “is in a sense necessarily a reconstruction based on hindsight reasoning.” (Office Action at 2.)

The Examiner also took the position that the affirmative texture masking limitation added to the claims in the April 15, 2004 Response is “implicit and/or inherent in the broad combined disclosure of the prior art.” (*Id.*)

Claimed Subject Matter is Not Inherently Disclosed by the Cited Documents

Texture masking was added as an affirmative limitation to the claimed subject matter in the April 15, 2004 Response. The Examiner contended that such a limitation is “implicit and/or inherent in the broad combined disclosure of the prior art.”

It is well settled that “that which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.” *In re Spormann*, 150 USPQ 449, 452 (CCPA. 1966). Inherency, however may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 40 USPQ 665, 667 (CCPA 1939): Nonetheless, the

examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ 2d 1461, 1464 (BPAI 1990) When the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the prior art (citing *In re Yates*, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981). *In re Rijckaert*, 9 F.3d 1531, 1533, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993)).

The Examiner asserted that the “prior art has disclosed the same composition structure, the same components, and the same particle sizes as that claimed by applicant.” (Paper No. 20040628 at 3.) The Examiner further asserted that “[i]t is the position of the Examiner that the prior art has disclosed the same basic structure of the instantly claimed invention.” (Paper No. 20040902 at 2.) With all due respect, it is not seen where the Examiner’s assertions are supported by the record in the captioned case.

For example, it is the Examiner’s position that “the cited documents affirmatively disclose the same particle size as that claimed by the applicant.” The independent claims of the captioned application are directed to, among other things, “a plurality of active agent particles having an average size of greater than 50 μm .” It is not seen where Lee discloses any particle size for anything, much less the claimed average particle size of the active agent particles. Friend discloses particular particle sizes for microcapsules, see e.g., col. 8, lns. 31-36. Table 1 and Table 2 in Friend appear to disclose that the mean particle size for ranitidine from Glaxo as being granular. It is unclear what specific particle size “granular” is intended to cover. Due to the lack of any specific guidance as to what “granular” is intended to mean, it is not seen where a disclosure of “granular” discloses the claimed active agent particle sizes. Furthermore, the record appears devoid of any specific reason why one skilled in the art would reasonably infer that the affirmatively claimed active agent particle sizes would be disclosed by a “granular” form of ranitidine hcl from Glaxo. For this reason, the rejection is improper and should be withdrawn.

By way of an additional example, it is the Examiner’s position that “the same composition structure as that claimed by the applicant” is affirmatively disclosed by the cited documents. However, it is not seen in this record where there is any disclosure or

suggestion for the claimed weight ratio of active agent particles to shell in any document cited by the Examiner. For this additional reason, the rejection is improper and should be withdrawn.

In Paper No. 20040902, the Examiner criticized the claims presented in the captioned application for not showing a “critical difference” in structure over the cited documents. Likewise in Paper No. 20031222, the Examiner opined that the burden shifted to the applicant to demonstrate how the weight ratio of active agent particles to the outer shell, among other things, are critical features. (20031222 at 3.) First, the burden only shifts to the applicant when a *prima facie* rejection has been made. Because there has been no *prima facie* case of obviousness made in this record, there has been no shift in the burden. The burden in the present case still lies with the Examiner. Second, as discussed above, the Examiner most recently took the position that the cited documents disclose “the same composition structure as that claimed by the applicant.” Such composition structure includes, but is not limited to, the claimed weight ratio and the claimed particle size. Because it is not seen where in the cited documents such disclosure or suggestion can be found, there is no *prima facie* rejection. For this reason, the burden has not shifted from the Examiner. Therefore the rejection is not proper and should be withdrawn.

Cited Documents are Not Properly Combinable

The Examiner reasoned that “one of ordinary skill would be motivated to incorporate the composition disclosed in Friend into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug.” (Paper No. 20031222 at 3.) The fact that Friend discloses “that the disclosed compositions may be incorporated into chewable tablets” provided the springboard for the Examiner to opine that “one of ordinary skill in the art could combine the disclosure of the prior art with a reasonable expectation of success.” (*Id.*)

One of the advantages of Lee’s invention was the alleged “excellent stability.” The Examiner’s attention is directed to column 3, lines, 31-53. In this passage, Lee describes the fact that “the chewable tablet of the present invention is prepared by the process in which the [drug] is mixed with the jelly or a chewable base at room

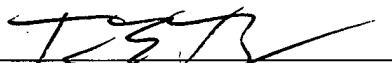
temperature." Such preparation was, according to Lee, the reason why Lee's chewable tablet had "excellent stability."

Contrary to Lee's room temperature method, Friend heats a mixture to 80°C until all of the polymer is dissolved, adds the drug to the polymer mixture, and stirs at 450 rpm for 1 hour. (Friend, col. 11, Example 1.) The resulting mixture was then allowed to cool with stirring at 450 rpm at about 0.5°C/min for 1 hour to a final temperature of about 50°C. (*Id.*) Friend further cautions that "care must be taken not to heat to a temperature which could degrade the drug." (Col. 5, lns. 31-32.)

It is not seen where one of ordinary skill in the art would be motivated to further taste mask a drug by applying heat in the process of making the final product where Lee's invention specifically states that the chewable tablet formulation has "excellent stability" because it is produced at room temperature. It appears that Lee teaches away from Friend. For this reason, it is not believed the cited documents are properly combinable and the rejection should, therefore, be withdrawn.

Accordingly, for the reasons set forth above, withdrawal of the rejections, and allowance of the claims is respectfully solicited

Respectfully submitted,

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CLAIMS APPENDIX

Claim 1 (previously presented): A texture masking oral dosage form comprising

- (a) a unitary soft core comprising a plurality of active agent particles having an average size of greater than about 50 μm and
- (b) a brittle shell encasing the soft core, wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0 in the texture masking oral dosage form.

Claim 2 (previously presented): An oral dosage form of claim 1, wherein the weight ratio of active agent particles to shell being from about 1.0:2 to about 1.0:12.

Claim 3 (previously presented): An oral dosage form of claim 2, wherein the weight ratio of particles to shell being from about 1.0:4 to about 1.0:9.

Claim 4 (original): An oral dosage form of claim 1, wherein the soft core is pectin based.

Claim 5 (previously presented): An oral dosage form of claim 1, wherein the soft core is gelatin based.

Claim 6 (previously presented): An oral dosage form of claim 1, wherein the soft core has a hardness of about 1 to about 8 kp/cm².

Claim 7 (previously presented): An oral dosage form of claim 1, wherein the active agent is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.

Claim 8 (original): An oral dosage form of claim 7, wherein the active agent is acetaminophen or ibuprofen.

Claim 9 (original): An oral dosage form of claim 8, wherein the active agent is acetaminophen.

Claim 10 (previously presented): An oral dosage form of claim 8, wherein the active agent is ibuprofen.

Claim 11 (previously presented): An oral dosage form of claim 3, wherein the active agent is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.

Claim 12 (original): An oral dosage form of claim 11, wherein the active agent is acetaminophen or ibuprofen.

Claim 13 (original): An oral dosage form of claim 12, wherein the active agent is acetaminophen.

Claim 14 (original): An oral dosage form of claim 12, wherein the active agent is ibuprofen.

Claim 15 (previously presented): A texture masking oral dosage form comprising

- (a) a unitary soft core comprising a plurality of acetaminophen particles having an average size of greater than about 50 μm and
- (b) a brittle shell enveloping the soft core, wherein the weight ratio of active agent to shell being from about 1.0:4 to about 1.0:9 in the texture masking oral dosage form.

Claim 16 (currently amended): A texture masking oral dosage form comprising

- (a) a unitary soft core comprising a plurality of ibuprofen particles having an average size of greater than about 50 μm and
- (b) a brittle shell enveloping the soft core, wherein the weight ratio of particles to shell being from about 1.0:4 to about 1.0:915 in the texture masking oral dosage form.

Claim 17 (currently amended): A texture masking oral dosage form comprising

- (a) a unitary soft core comprising a plurality of active agent particles having an average size of greater than about 50 μm and
- (b) a brittle shell encasing the soft core, wherein the weight ratio of active agent particles to shell being from about 1.0:0.5 to about 1.0:15 and wherein the soft core has a hardness of about 1 to about 8 kp/cm²15 in the texture masking oral dosage form.

Claim 18 (previously presented): An oral dosage form of claim 1, wherein the weight ratio of active agent particles to shell being from about 1.0:2 to about 1.0:12.

Claim 19 (previously presented): An oral dosage form of claim 18, wherein the weight ratio of active agent particles to shell being from about 1.0:4 to about 1.0:9.

Claim 20 (previously presented): An oral dosage form of claim 17, wherein the soft core is pectin based.

Claim 21 (previously presented): An oral dosage form of claim 1, wherein the soft core is gelatin based.

Claim 22 (previously presented): An oral dosage form of claim 17, wherein the active agent is selected from the group consisting of acetaminophen, ibuprofen, pseudoephedrine, dextromethorphan, diphenhydramine, chlorpheniramine, calcium carbonate, magnesium hydroxide, magnesium carbonate, magnesium oxide, aluminum hydroxide, mixtures thereof, and pharmaceutically acceptable salts thereof.

Claim 23 (previously presented): An oral dosage form of claim 22, wherein the active agent is acetaminophen or ibuprofen.

Claim 24 (previously presented): An oral dosage form of claim 23, wherein the active agent is acetaminophen.

Claim 25 (previously presented): An oral dosage form of claim 23, wherein the active agent is ibuprofen.

Serial No. 09/966,441

EVIDENCE APPENDIX

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RELATED PROCEEDINGS APPENDIX